

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44bis.3(c) and 72.2)

To:

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Applicant's or agent's file reference
M/44234-PCT

IMPORTANT NOTIFICATION

International application No.
PCT/EP2004/010346

International filing date (day/month/year)
15 September 2004 (15.09.2004)

Applicant

BASF AKTIENGESELLSCHAFT et al

1. Transmittal of the translation to the applicant.

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

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The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MY, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Agnes Wittmann-Regis

TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference M/44234-PCT	FOR FURTHER ACTION		See Form PCT/PEAA/16
International application No. PCT/EP2004/010346	International filing date (day/month/year) 15. 09. 2004	Priority date (day/month/year) 16. 09. 2003	
International Patent Classification (IPC) or national classification and IPC C12N15/81, C12N15/62			
Applicant BASF AKTIENGESELLSCHAFT			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>15</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. 1 and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>	
Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. 1 Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-41 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. 1-28 _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* _____ received by this Authority on _____
- nos.* _____ received by this Authority on _____
- ☒ the drawings:
- sheets 1/9-9/9 _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c))
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____

* If item 4 applies, none or all of those sheets may be marked "superceded."

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Box No. IV

Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees the applicant has:
- ☐ restricted the claims.
 - ☒ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ neither restricted the claims nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
- ☐ complied with.
 - ☒ not complied with for the following reasons:

See Supplemental Box

4. Consequently, this report has been established in respect of the following parts of the international application:

☒ all parts.☐ the parts relating to claims Nos. _____

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement
1. Statement	
Novelty (N)	Claims _____ YES Claims 1-28 _____ NO
Inventive step (IS)	Claims _____ YES Claims 1-28 _____ NO
Industrial applicability (IA)	Claims 1-28 _____ YES Claims _____ NO
2. Citations and explanations (Rule 70.7)	<p>The present application describes an expression construct that contains a shuttle peptide construct that can be processed by yeast cells. The shuttle peptide construct consists of a signal peptide that is linked to a shuttle peptide that can be secreted by yeast cells. The shuttle peptide construct can also be linked to an additional target protein, for example hydrophobin.</p> <p>This report makes reference to the following documents (the numbering will be retained throughout the proceedings):</p> <p>D1: IMAI Y ET AL: "THE FISSION YEAST MATING PHEROMONE P-FACTOR: 1ST MOLECULAR STRUCTURE, GENE STRUCTURE, AND ABILITY TO INDUCE GENE EXPRESSION AND G1 ARREST IN THE MATING PARTNER" GENES AND DEVELOPMENT, COLD SPRING HARBOR, NY, US, Vol. 8, No. 3, 1994, pages 328-338</p> <p>D2: WO 96/41882 A (PROEFSTATION VOOR DE CHAMPIGNONCULTUUR; RIJKSLANDBOUWUNIVERSITEIT</p>

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

WAGE) 27 December 1996

D3: WO 02/46369 A (SEPTEGEN LIMITED; DAVEY, JOHN)
13 June 2002

D4: JP 06 327481 A (ASAHI GLASS CO LTD)
29 November 1994

D5: WO03053383 (L'OREAL; VIC, GABIN) 03 July 2003

D6: WO 02/20651 A (ZYMOGENETICS, INC) 14 March
2002

The following statement concerns group 1
(consisting of subgroups 1.1 - 1.3; claims 1-24
(all in part), 25-28 (all in full)), as described
in the supplemental box

1. In view of the disclosures of D1, D3 and D4 described in the supplemental box, the current application does not meet the requirements of PCI Article 33(1) because the subject matter of claims 1-24 lacks novelty (PCT Article 33(2)). In addition, the secretion of hydrophobin by yeast cells has already been disclosed (e.g. D2: page 17, paragraph 5). Regarding the subject matter of claims 25-28, the applicant should note that a product is not rendered novel by the fact that it is produced by means of a possibly new method (PCI Guidelines Appendix A5.26[1], 2004).

D5 discloses the use of hydrophobin to treat fibres (the entire document).

The subject matter of claims 1-28 thus lacks novelty (PCT Article 33(2)).

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability:
citations and explanations supporting such statement

2. The subject matter of independent claims 1, 12, 13, 16, 21, 23 and 24 lacks novelty (PCT Article 33(2)).

D6 discloses a human pheromone protein, namely ZHMUP-2 (page 8, lines 20 and 21), which is linked so as to be processable to a yeast pheromone preprotein (pages 43 and 44) and is fused so as to be processable to another protein (page 18, lines 24-28; page 44, paragraph 3; page 46).

The following statement concerns group 2 (claims 1-24 (all in part)), as described in the supplemental box

3. The above objections relating to novelty in respect of group 1 also apply to group 2 and therefore the subject matter of claims 1-24 lacks novelty (PCT Article 33(2)). The applicant should note that D3 in particular also discloses the expression of heterological proteins.

Inventive step

4. Since the subject matter of claims 1-28 lacks novelty (see above), it also fails to involve an inventive step (PCT Article 33(3)).

Industrial applicability

5. The subject matter of claims 1-28 is industrially

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

applicable (PCT Article 33(4)).

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The following statement concerns group 1
(consisting of subgroups 1.1 - 1.3; claims 1-24
(all in part), 25-28 (all in full)), as described
in the supplemental box

6. The subject matter of claims 25-28 characterises products in terms of a method for the production thereof ('product-by-process' claim). Claims directed to products which are defined in terms of the process for the production thereof meet the requirements of PCT Article 6 only if the application contains no other information which would allow the applicant to define the product in terms of its composition, structure, or other verifiable parameter. Products may therefore be defined in terms of a process for the production thereof only on the condition that no other parameters are available for characterising the product, which is not, however, the case in the current application.

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
- a. type of material
- ☒ a sequence listing
- ☐ table(s) related to the sequence listing
- b. format of material
- ☒ in written format
- ☒ in computer readable form
- c. time of filing/furnishing
- ☒ contained in the international application as filed
- ☒ filed together with the international application in computer readable form
- ☐ furnished subsequently to this Authority for the purposes of search and/or examination
- ☐ received by this Authority as an amendment* on _____
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

The sequence listing in the description, pages 1-34, as originally filed

* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box IV**Lack of unity of invention**

This authority has determined that the international application contains multiple inventions that do not meet the requirement for unity of invention (PCT Rule 13.1 and 13.2), as follows:

Group 1:

Subgroup 1.1: claims 1-5, 8, 9, 12-20, 23, 24 (all in part)

Expression construct that contains a shuttle peptide construct that can be processed by yeast cells. The shuttle peptide construct consists of a signal peptide that is linked with a shuttle peptide that can be secreted by yeast cells. The shuttle peptide construct is from a yeast.

Subgroup 1.2: claims 1-24 (all in part)

Expression construct that contains a shuttle peptide construct that can be processed by yeast cells. The shuttle peptide construct consists of a signal peptide that is linked with a shuttle peptide that can be secreted by yeast cells. The shuttle peptide construct is from a yeast and in

Supplemental Box

addition contains a homologous target protein.

Subgroup 1.3: claims 25-28 (all in full)

Hydrophobin and the use thereof.

N.B.: the above subgroups are not necessarily linked by a common inventive concept.

Group 2: claims 1-24 (all in part)

Expression construct that contains a shuttle peptide construct that can be processed by yeast cells. The shuttle peptide construct consists of a signal peptide that is linked with a shuttle peptide that can be secreted by yeast cells. The shuttle peptide construct is from a yeast and in addition contains a heterologous target protein.

The reasons are as follows:

The application is based on the concept of developing means with which proteins expressed in yeast can be secreted from the yeast cells into the surrounding medium (see page 3, lines 7-10 of the application).

This concept was already realised, however in documents D1, D3 and D4.

Document D1 discloses (the references between parentheses refer to that document) an expression

Supplemental Box

construct which contains a shuttle peptide construct that can be processed by yeast cells. The shuttle peptide construct consists of a signal peptide which is linked to four shuttle peptides that can be processed and secreted by yeast cells; the last one is a homologous target protein which is linked so as to be processable to the C terminal of the shuttle peptide construct. The shuttle peptide construct is from *Schizosaccharomyces pombe* (see the entire document).

Document D3 discloses (the references between parentheses refer to that document):

- the 319 nt long SEQ ID NO:27, in which nt 12-182 is 100% identical to the entire SEQ ID NO:1, nt 12-71 is 100% identical to the entire SEQ ID NO:3 and nt 102-182 is 100% identical to the entire SEQ ID NO:5 of the current application;
- the 99 aa long SEQ ID NO:13, in which aa 1-57 is 100% identical to the entire SEQ ID NO:2 of the current application;
- an expression construct which contains a shuttle peptide construct that can be processed by yeast cells. The shuttle peptide construct consists of a signal peptide that is linked to a shuttle peptide which can be secreted by yeast cells, both based on the pheromone preprotein. The shuttle peptide construct is from

Supplemental Box

Schizosaccharomyces pombe (page 17;
figure 7A).

Document D4 discloses (the references between
parentheses refer to that document):

- a 1705 nt long sequence, in which nt 848-1018 is 100% identical to the entire SEQ ID NO:1, nt 848-907 is 100% identical to the entire SEQ ID NO:3 and nt 938-1018 is 100% identical to the entire SEQ ID NO:5 of the current application (pages 6-8);
- a 201 aa long sequence, in which aa 1-57 is 100% identical to the entire SEQ ID NO:2 of the current application (pages 7 and 8);
- an expression construct which contains a shuttle peptide construct that can be processed by yeast cells. The shuttle peptide construct consists of a signal peptide that is linked to a shuttle peptide which can be secreted by yeast cells. The shuttle peptide construct is from *Schizosaccharomyces pombe* and consists of the pheromone preprotein (the entire document).

There is therefore no single general inventive concept linking the subjects of claims 1-28 of the current application (PCT Article 3(4)(iii) and Rule 13.1).

A comparison of the current groups of claims with the stated documents shows that the following

Supplemental Box

features make a contribution over the prior art and can therefore be regarded as special technical features pursuant to PCT Rule 13.2:

Group 1:

Subgroup 1.1: no special technical feature;

Subgroup 1.2: no special technical feature;

Subgroup 1.3: hydrophobin and the use thereof.

Group 2: secretion of a heterologous target protein.

In addition, the secretion of hydrophobin by yeast cells has already been disclosed (e.g. D2: page 17, paragraph 5). Regarding the subject matter of claims 25-28, the applicant should note that a product is not rendered novel by the fact that it is produced by means of a possibly new method (PCT Guidelines Appendix A5.26[1], 2004).

It is clear from the above that the inventions described in claims 1-28 are different and that there is no special technical feature in the sense of PCT Rule 13.2 that is common to those inventions.

Consequently, neither on the basis of the problems addressed by each invention nor on the basis of the solutions thereto defined by the special technical features of each invention can a technical relationship be determined amongst the inventions which results in a single general

Supplemental Box

inventive concept.

Consequently, the stated groups of claims do not meet the requirements for unity of invention pursuant to PCT Rule 13.1 and 13.2 on the basis of either the special technical features of the claims or the problems solved thereby.